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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,375	11/09/2001	John Tallman	99,130-J	5633

7590 10/05/2004

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/045,375	TALLMAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's timely election (July 19, 2004) of Group IV is noted. However, after further consideration, a new restriction requirement is issued below.

#### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11, drawn to methods of screening compounds for cognitive enhancing activity, classified in class 436, subclass 501.
- II. Claims 12-23, drawn to methods of screening compounds for hypnotic activity, classified in class 436, subclass 501.
- III. Claims 24-35, drawn to methods of screening compounds for anxiolytic activity, classified in class 436, subclass 501.
- IV. Claims 36-47, drawn to methods of screening compounds for antidepressant activity, classified in class 436, subclass 501.
- V. Claim 48, drawn to methods of marketing a drug with hypnotic activity, classified in class 725, subclass 705.
- VI. Claim 49, drawn to methods of marketing a drug with anxiolytic activity, classified in class 725, subclass 705.
- VII. Claim 50, drawn to methods of marketing a drug with antidepressant activity, classified in class 725, subclass 705.

The inventions are distinct, each from the other because of the following reasons:

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Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-IV are directed to methods that are distinct both physically and functionally, e.g. they require different animal models of distinct aspects of physiology, and are not required one for the other. Group I requires methods of screening compounds for cognitive enhancing activity, which is not required by any of the other groups. Group II requires methods of screening compounds for hypnotic activity, which is not required by any of the other groups. Group III requires methods of screening compounds for anxiolytic activity, which is not required by any of the other groups. Group IV requires methods of screening compounds for antidepressant activity, which is not required of any of the other groups. Further, although a search of one method may overlap that of another, the searches would not be coextensive; a search of any one of the methods could not be relied upon to provide art that is anticipatory of any other method.

Although the inventions of Group II and Group V are directed to methods and not products, they are related essentially as subcombination (Group II) and combination (Group V).

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because one would expect that a drug identified by the method Group II would also be identified by conventional methods of finding hypnotic drugs, thus the

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additional elements gaining regulatory approval and marketing do not require the particulars of the subcombination element. Further the subcombination has separate utility such as to identify compounds to be used solely for research purposes to study the role of the different GABA receptor subtypes. Further a search of both of these inventions would not be coextensive and considerably burdensome, as evidenced by their separate classification in the art. The same reasoning applies to the inventions of Groups III and VI and to Groups IV and VII.

The following inventions are unrelated because the use of one is not required for the use of the other:

Group V is not related to any of Groups I, II, IV, VI, and VII

Group VI is not related to any of Groups I, II, IV, V, and VII

Group VII is not related to any of Groups I-III, V, and VI

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Conclusion***

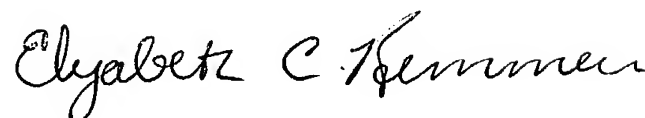
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



ELIZABETH KEMMERER  
PRIMARY EXAMINER

October 4, 2004